USSN 09/975,350
Art Unit: 1618

REMARKS

Status of Claims

Upon entry of the present amendments, claims 1-4, 8-51, and 55-65 will be pending in this application. Claims 1-4, 8-51, and 55-58 are rejected.

Applicants gratefully acknowledge the Examiner's favorable reconsideration and withdrawal of the previous rejections of claims 1-5 and 7-58 under 35 U.S.C. §112. and claims 1, 3-5, 14, 15, 32-35, and 44 for obviousness type double patenting.

Claims 2 and 36 are redrafted in independent format.

Claims 2, 3, 8, 10, 14, 19, 32, 43, 44, 55, 57, and 58 are amended to remove multiple dependencies.

Claims 1, 2, 36, and 42 are amended to recite a "liquid" composition. Support for this amendment can be found on page 13, lines 27-29, page 14, line 24 to page 15, line 3, and page 15, lines 28-30.

Claims 15 and 19 are amended to recite tetraglycol. Support for this amendment can be found on page 9, line 1.

Claims 11, 37, 38, 42, and 51 are amended to better present the invention and to correct claim language informalities.

Claim 40 is amended to depend on claim 36.

Support for new claim 59 can be found on page 8, line 31 to page 9, line 7.

New claims 60-65 are based on claims 43, 44, 55, and 57.

No new matter has been added by way of these amendments.

Claim Rejections

Reconsideration and allowance of all claims is hereby respectfully requested in light of the following Remarks.

Rejections under 35 U.S.C. §102

Grebow:

Claims 1-4, 32, 33, 36, 37, 39, 41-44, 47, 48, 51, and 58 are rejected under 35 U.S.C. §102(b) as being anticipated by Grebow, et al. (US 5,618,845).

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"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference" (*Verdegall Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631; MPEP § 2131). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" (*In re Robertson*, 169 F.3d 743, 745; MPEP § 2112(IV))

As amended, claim 1 recites: "A non-aqueous particle-forming composition comprising a modafinil compound and at least one *surfactant*, characterized in that the composition *spontaneously* forms an aqueous, liquid, homogeneous, *stable* composition of *non-crystalline* particles when contacted with an aqueous medium." The *italicized* elements of claim 1 are discussed in detail below.

Surfactant

The composition of claim 1 requires a surfactant. The Examiner does not allege that Grebow expressly discloses a surfactant. Instead, the Examiner alleges that Grebow inherently discloses a surfactant because "emulsions by their nature contain surfactants/emulsifiers."

According to MPEP § 2112(IV), to establish the inherency of a surfactant in Grebow, the extrinsic evidence must make clear that a surfactant is necessarily present in the Grebow emulsion. There is no extrinsic evidence of record demonstrating that surfactants are necessarily present in emulsions. On the contrary, Applicants provide the following extrinsic evidence demonstrating that the opposite it true:

1. "Emulsion" defined in Merriam-Webster's Medical Dictionary (© 2002, Merriam-Webster, Inc.):

> "A system (as fat in milk) consisting of a liquid dispersed with or without an emulsifier in an immiscible liquid usually in droplets of larger than colloidal size" (emphasis

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added).

2. U.S. Patent No. 4,151,143 ("Surfactant-free polymer emulsion coating composition and method for preparing same"). The '143 patent discloses an emulsion composition without a surfactant.

This extrinsic evidence indicates that surfactants are not necessarily present in emulsions. Therefore, the extrinsic evidence fails to make it clear that a surfactant is necessarily present in the Grebow emulsion. Accordingly, Grebow does not inherently disclose a surfactant.

Spontaneously

When contacted with an aqueous medium, the composition of claim 1 must *spontaneously* form an aqueous, liquid, homogeneous, stable composition of non-crystalline particles. According to the specification, "spontaneously" means "upon mixing, without external mechanical agitation" (page 15, lines 7-8). The Examiner does not allege that Grebow expressly or inherently discloses a composition that spontaneously forms an aqueous, liquid, homogeneous, stable composition of non-crystalline particles when contacted with an aqueous medium.

According to MPEP § 2112(IV), to establish that the Grebow suspension or emulsion formed spontaneously, the extrinsic evidence must make clear that the Grebow suspension or emulsion necessarily formed spontaneously. There is no extrinsic evidence of record demonstrating that suspensions or emulsions necessarily form spontaneously. On the contrary, Applicants provide the following extrinsic evidence demonstrating that the opposite is true:

1. Grebow discloses formation of a modafinil suspension at col. 8, lines 23-30:

> "In the first experiment, 500 ml of deionized water was put in a 1- liter beaker and 50 mg of [modafinil] was added. The suspension was stirred constantly with a 5 cm Teflon-coated magnetic stir bar and a magnetic stir plate (Thermolyne model #546725). Samples of 1 ml each were taken at times 0, 1, 5, 10, 15, 20, 25, 30, 40, 50, and 60 minutes, with each sample being replaced with 1 ml of deionized water. The stir plate speed setting

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was "2" for the first 20 minutes, and "7" from 20 to 60 minutes. Each sample was immediately filtered through a 0.45 μm filter, to remove undissolved particles." (emphasis added)

The Grebow suspension was formed by constant stirring for 60 minutes. Given that significant external mechanical agitation was employed, the suspension was not formed spontaneously.

2. Emulsions. *Kirk-Othmer Encyclopedia of Chemical Technology*, 3d ed.; Wiley & Sons: New York, 1979; Vol. 8, pp 900-930 describes on pages 920-23 the methods and equipment used to prepare emulsions, such as stirring, aeration, propeller agitation, turbine agitation, colloid mill, homogenization, and ultrasonics:

> "The purpose of the emulsification equipment, whether simple or complex, is to break up or disperse the internal phase in the external phase, so that the particle size of the resulting emulsion is sufficiently small to retard coalescence and resulting breakdown of the emulsion for the required time of stability." (p. 920)

This reference teaches that external mechanical agitation is commonly used to prepare emulsions, i.e., emulsions are not formed spontaneously.

This extrinsic evidence indicates that suspensions or emulsions are not necessarily formed spontaneously. Therefore, the extrinsic evidence fails to make it clear that the Grebow suspension or emulsion necessarily formed spontaneously. Accordingly, Grebow does not inherently disclose spontaneous formation of an aqueous, liquid, homogeneous, stable composition of non-crystalline particles when contacted with an aqueous medium.

Stable

Claim 1 requires that when the non-aqueous composition is contacted with an aqueous medium, the resulting aqueous, liquid, homogeneous composition of non-crystalline particles is *stable*. According to the specification, in a stable composition "the particles do not readily or irreversibly aggregate, coalesce, or otherwise revert back to two separate bulk phases." (page 15,

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lines 31-32) The Examiner does not allege that Grebow expressly discloses a stable composition. Instead, the Examiner alleges that Grebow inherently discloses a stable suspension: "The composition of Grebow encompasses stable and unstable suspensions because the prior art does not exclude stable suspensions and thus the suspension of Grebow would be inherently stable."

According to MPEP § 2112(IV), to establish that the Grebow suspension is inherently stable, the extrinsic evidence must make clear that the Grebow suspension is necessarily stable. There is no extrinsic evidence of record demonstrating that suspensions are necessarily stable. On the contrary, the Examiner acknowledges that some suspensions are not stable: "[t]he composition of Grebow encompasses stable and unstable suspensions."

Further evidence that the Grebow suspension is not necessarily stable includes:

1. Grebow discloses an unstable suspension at col. 8, lines 23-30:

> "In the first experiment, 500 ml of deionized water was put in a 1-liter beaker and 50 mg of [modafinil] was added. The suspension was stirred constantly with a 5 cm Teflon-coated magnetic stir bar and a magnetic stir plate (Thermolyne model #546725). Samples of 1 ml each were taken at times 0, 1, 5, 10, 15, 20, 25, 30, 40, 50, and 60 minutes, with each sample being replaced with 1 ml of deionized water. The stir plate speed setting was "2" for the first 20 minutes, and "7" from 20 to 60 minutes. Each sample was immediately filtered through a 0.45 μm filter, to remove undissolved particles." (emphasis added)

The Grebow suspension was stirred constantly for 60 minutes. A suspension that must constantly be stirred is not stable.

2. Emulsions. *Kirk-Othmer Encyclopedia of Chemical Technology*, 3d ed.; Wiley & Sons: New York, 1979; Vol. 8, pp 900-930 states on page 900 that "[e]mulsions are inherently unstable systems and the risk of deteriorating during storage is greater than with a nonemulsified product."

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This extrinsic evidence indicates that suspensions or emulsions are not necessarily stable systems. Therefore, the extrinsic evidence fails to make it clear that the suspension of Grebow is necessarily stable. Accordingly, Grebow does not inherently disclose a stable composition.

Non-crystalline

Claim 1 requires that when the non-aqueous composition is contacted with an aqueous medium, the resulting aqueous, liquid, homogeneous, stable composition comprises *non-crystalline* particles. The Examiner alleges that "Grebow discloses suspensions containing modafinil and in the suspension modafinil is not crystalline and the particles of modafinil are suspended in the solvent." Applicants are unsure if the Examiner alleges that Grebow expressly or inherently discloses non-crystalline modafinil particles.

Regarding express disclosure, Grebow discloses the following suspension of modafinil particles:

> "In the first experiment, 500 ml of deionized water was put in a 1- liter beaker and 50 mg of [modafinil] was added. The suspension was stirred constantly with a 5 cm Teflon-coated magnetic stir bar and a magnetic stir plate (Thermolyne model #546725). Samples of 1 ml each were taken at times 0, 1, 5, 10, 15, 20, 25, 30, 40, 50, and 60 minutes, with each sample being replaced with 1 ml of deionized water. The stir plate speed setting was "2" for the first 20 minutes, and "7" from 20 to 60 minutes. Each sample was immediately filtered through a 0.45 μm filter, to remove undissolved particles." (col. 8, lines 23-30)

Grebow does not expressly disclose whether the modafinil particles in the suspension were crystalline or non-crystalline.

According to MPEP § 2112(IV), to establish that Grebow inherently discloses non-crystalline particles, the extrinsic evidence must make clear that the Grebow suspension necessarily contained non-crystalline particles. There is no extrinsic evidence of record demonstrating that modafinil suspensions necessarily contain non-crystalline particles. On the

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contrary, Grebow teaches that the opposite is true. Grebow states that U.S. Patent No. 4,177,290 (the '290 patent) provides an appropriate method for preparing modafinil particles (*see* col. 9, line 61 to col. 10, line 13). The '290 patent teaches the following procedure for preparing modafinil:

> "14.39 g (0.056) of benzhydrylthioacetamide are placed in a balloon flask and 60 ml of acetic acid and 5.6 ml of H_2O_2 (about 110 volumes) are added. The mixture is left in contact for one night at 40° C. and about 200 ml of water are then added; the [modafinil] crystallises. By recrystallisation from methanol, 11.2 g of [modafinil] are obtained." (Example 1, emphasis added)

The procedure of the '290 patent provides crystalline modafinil particles.

This extrinsic evidence indicates that suspensions do not necessarily contain non-crystalline modafinil particles. Therefore, the extrinsic evidence fails to make it clear that the suspension of Grebow necessarily contained non-crystalline particles. Accordingly, Grebow does not inherently disclose non-crystalline modafinil particles.

In conclusion, Grebow fails to expressly or inherently disclose the "surfactant," "spontaneously," "stable," or "non-crystalline" limitations of independent claim 1. Independent claim 36 contains each of these limitations. Independent claim 2 contains each of these limitations except "spontaneously." Therefore, Grebow fails to expressly or inherently disclose each limitation of independent claims 1, 2, or 36, and Grebow does not anticipate claims 1, 2, or 36 or any claim dependent thereon. Applicants respectfully request that this rejection be withdrawn.

Nguyen:

Claims 1-4, 6, 7, 11, 14, 15, 32, 33, 36, 37, 39, 47, and 51 are rejected under 35 U.S.C. §102(b) as being anticipated by Nguyen et al. (US 5,843,347). Applicants previously argued that Nguyen fails to disclose a composition that spontaneously forms an aqueous, homogeneous, stable composition when contacted with an aqueous medium. The Examiner alleges that Applicants' argument is not persuasive because claim 1 is directed to a

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composition/product.

The Examiner appears to have read "spontaneously forms" and the language thereafter out of claim 1 and not accorded this limitation patentable weight. Claim 1 is now amended to more clearly indicate that this language is intended to recite a characteristic property of the claimed composition.

MPEP §§ 2112(III) – 2112.01(II) acknowledges that a composition may be claimed in terms of a property or characteristic, and that the claimed property or characteristic is accorded patentable weight. Examples of composition properties or characteristics that can be claimed include strength or flexibility, suitability for a particular purpose, or behavior in a given environment (e.g., dissolution rate in water). Pursuant to MPEP §§ 2112(III) – 2112.01(II), a composition claimed in terms of a property or characteristic is not anticipated if the prior art composition lacks the claimed property or characteristic.

Numerous U.S. patents have been granted for compositions claimed in terms of a property or characteristic. Some recent examples include:

U.S. Patent No. 7,070,803

1. A controlled release pharmaceutical composition for oral use comprising midodrine (ST 1085) or a pharmaceutically acceptable salt thereof and/or its active metabolite desglymidodrine (ST 1059) or a pharmaceutically acceptable salt thereof,

wherein the in vitro release rate of midodrine and/or desglymidodrine has the following course of events

i) a relatively fast first initial release followed by

ii) a steady release or a slower release than in step i) above, which is followed by

iii) a second rise in release rate that takes place 5-10 hours after start of an in vitro dissolution test and, finally,

iv) a decline in release rate

wherein the composition upon administration provides a relatively fast peak plasma concentration of desglymidodrine, and a therapeutically effective plasma concentration of desglymidodrine is maintained for at least about 9 hours.

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Applicants note that controlled release compositions of midodrine were known before the priority date of the '803 patent (*see* col. 1, lines 40-44 of the '803 patent). Therefore, the controlled release midodrine composition of the '803 patent is patentably distinct from the controlled release midodrine compositions of the prior art because of the italicized "wherein" clauses. In other words, the "wherein" clauses have patentable weight. Applicants respectfully point out that the "wherein" clauses recite specific properties of the claimed composition.

U.S. Patent No. 7,053,034

3. The composition according to claim 1 *wherein said pH sensitive micro-sphere degrades or dissolves when said pH sensitive micro-sphere contacts a solution having a pH in the range of about 3 to about 12.*

Applicants note that pursuant to 37 C.F.R. § 1.75(c), a dependent claim must further limit a preceding claim (MPEP § 608.01(n)). Applicants submit that because claim 3 of the '034 patent is a dependent claim, and the only limitation in claim 3 is a property limitation, the property limitation has patentable weight.

U.S. Patent No. 7,067,152

1. A controlled release cosmetic composition for delivery to skin or lips consisting of: a plurality of solid nano-spheres, said solid nano-spheres consisting of a hydrophobic material and a first active agent, said first active agent is a cooling agent and one or more agents selected from the group consisting of fragrance, flavor, cosmetic agent, dermatological agent, and pharmaceutical agent, said plurality of nano-spheres being encapsulated in a moisture sensitive micro-sphere, and said moisture sensitive microsphere consisting of a moisture sensitive matrix material and a second active agent, encapsulated in said moisture sensitive matrix material, said second active agent is one or more of a cooling agent, fragrance, flavor, cosmetic agent, dermatological agent or pharmaceutical agent, *said moisture sensitive micro-sphere dissolves to release said second active agent and said plurality of nano-spheres upon contact with moisture from the skin or lips to provide a burst of said second active agent and said nano-spheres release said first active agent continuously thereafter for an extended period of time or said micro-sphere swells or softens upon contact with moisture from the skin or lips to slowly release said second active agent and said nano-spheres release said first active agent continuously thereafter for an*

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extended period of time.

U.S. Patent No. 7,063,862

1. A pharmaceutical composition, comprising:
a therapeutically active agent;
from about 0.1% to about 4.9% by weight of a swellable and water-soluble pharmaceutically acceptable polymer; and
from about 0.1% to about 30% by weight of a pharmaceutically acceptable acid, *wherein the pharmaceutical composition has a zero order release profile of the therapeutically active agent.*

U.S. Patent No. 6,231,888

1. A composition or drug delivery device for localized drug release in the colon, said composition or device comprising one or more drugs in a core, and a coating surrounding said core, said coating having an outer surface, wherein said coating comprises water insoluble hydrophilic particulate matter embedded in a water-insoluble carrier, *such that when said composition or device enters the gastrointestinal tract, said particulate matter absorbs liquid, thus forming channels that interconnect said core with said outer surface of said coating, and through which channels, said one or more drugs are released into the colon, such that at least one of said drugs is preferentially metabolized to a more active metabolite in the colon.*

Each of the above patents is directed to a composition, and each claims a composition in terms of a property or characteristic. The property or characteristic in U.S. Patent Nos. 7,070,803, 7,063,862, and 6,231,888 is the composition's ability to cause a specific result when contacted with the gastrointestinal tract. The property or characteristic in U.S. Patent No. 7,067,152 is the composition's behavior when contacted with moisture from the skin or lips. The property or characteristic in U.S. Patent No. 7,053,034 is the composition's behavior when contacted with a solution having a pH in the range of about 3 to about 12. In other words, each of the above recently issued patents claims a composition in terms of the result obtained when it is contacted with an aqueous medium.

The present application also claims a composition in terms of the result obtained when it

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is contacted with an aqueous medium. Specifically, amended claim 1 recites as a characteristic property of the composition that it spontaneously forms an aqueous, liquid, homogeneous, stable composition of non-crystalline particles when it is contacted with an aqueous medium. Applicants respectfully submit that this limitation should be given patentable weight by the Examiner, and must be expressly or inherently described in a single prior art reference for composition claim 1 to be anticipated.

Spontaneously

Claim 1 requires the composition to *spontaneously* form an aqueous, liquid, homogeneous, stable composition of non-crystalline particles when contacted with an aqueous medium. According to the specification, "spontaneously" means "upon mixing, without external mechanical agitation" (page 15, lines 7-8).

Nguyen discloses a process for preparing lyophilized particles comprising the steps of (1) preparing a pasty mixture from (a) an active ingredient, (b) a polymer having a molecular weight of greater than or equal to 10,000 Daltons, (c) a diluent, (d) water, and optionally (e) a surfactant; (2) extruding the pasty mixture and cutting the extrudate to give moist particles; (3) freezing the particles; and (4) drying the particles. As noted by the Examiner, step (1) of the Nguyen process involves homogenization such that the active ingredient is in the form of a solution, suspension or emulsion in the pasty mixture.

However, the Nguyen homogenization requires external mechanical agitation by, e.g., a mixer equipped with a rotary stirrer (col. 8, lines 17-24). Example 1 discloses dispersing the ingredients by means of a homogenizer operating at an angular velocity of 2,000 rpm for 2 minutes. Example 5 discloses homogenization of the mixture by means of an apparatus of the Turrax type operating at an angular velocity of 5,000 rpm for 5 minutes. Therefore, the Nguyen disclosure is limited to using external mechanical agitation to prepare the pasty mixture. Spontaneous formation is neither expressly nor inherently disclosed.

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Liquid

As amended, claim 1 requires the composition to spontaneously form an aqueous, *liquid*, homogeneous, stable composition of non-crystalline particles when contacted with an aqueous medium.

The disclosure of Nguyen is limited to a composition that when mixed with water forms a pasty mixture (col. 5, lines 3-8). The pasty mixture can be extruded and cut into regular shapes (col. 4, lines 25-29). The pasty mixture may be cut by means of a rotating knife or a blade pivoting with a reciprocal motion to produce small, substantially cylindrical rods (col. 5, lines 24-27). Applicants respectfully submit that a mixture that can be cut into shapes is semisolid, not liquid. A liquid is neither expressly nor inherently disclosed.

In conclusion, Nguyen fails to expressly or inherently disclose the "spontaneously" or "liquid" limitations of independent claim 1. Independent claim 36 contains each of these limitations. Independent claim 2 contains the "liquid" limitation. Therefore, Nguyen fails to expressly or inherently disclose each limitation of independent claims 1, 2, or 36, and Nguyen does not anticipate claims 1, 2, or 36 or any claim dependent thereon. Applicants respectfully request that this rejection be withdrawn.

Rejections under 35 U.S.C. §103

Grebow:

Claims 17, 18, 34, 35, 38, 45, 46, 49, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grebow et al. (US 5,618,845).

To establish a *prima facie* case of obviousness, the Examiner must demonstrate that a prior art reference teaches or suggests all of the limitations of the rejected claim (MPEP § 2142). As discussed above, the disclosure of Grebow is limited to a generic teaching of conventional tablets, capsules, powders, pills, liquid/suspensions or emulsions (col. 10, lines 18-21), and to a specific teaching of preparing a suspension using external mechanical agitation (col. 8, lines 22-31). There is no suggestion in Grebow of a composition that *spontaneously* forms an aqueous,

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liquid, stable composition of non-crystalline particles when contacted with water.

In view of the fact that Grebow fails to teach or suggest each limitation of the rejected claims, Grebow does not render the rejected claims obvious. Applicants respectfully request that this rejection be withdrawn.

Nguyen in view of Lafon:

Claims 8-10, 12, 13, 16-31, 34, 35, 38 and 40-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen et al. (US 5,843,347) in view of Lafon (US 5,180,745).

To establish a *prima facie* case of obviousness, the Examiner must demonstrate that a prior art reference teaches or suggests all of the limitations of the rejected claim (MPEP § 2142). As discussed above, the disclosure of Nguyen is limited to a composition that forms a pasty mixture, which can be extruded and cut into regular shapes (col. 4, lines 25-29). There is no suggestion in Nguyen of a composition that forms a liquid. Indeed, a liquid could not be extruded and cut into regular shapes, and so would change the principle of operation of the Nguyen reference (MPEP § 2143.02(VI)).

Lafon fails to cure the deficiencies of Nguyen. The Examiner relies upon Lafon for a disclosure that modafinil is used to treat Parkinson disease.

In view of the fact that Nguyen, alone or in combination with Lafon, fails to teach or suggest each limitation of the rejected claims, Nguyen and Lafon do not render the rejected claims obvious. Applicants respectfully request that this rejection be withdrawn.

Grebow in view of Lafon:

Claims 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grebow et al. (US 5,618,845) in view of Lafon (US 4,927,855).

As discussed above, the disclosure of Grebow is limited to a generic teaching of

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conventional tablets, capsules, powders, pills, liquid/suspensions or emulsions (col. 10, lines 18-21), and to a specific teaching of preparing a suspension using external mechanical agitation (col. 8, lines 22-31). There is no suggestion in Grebow to prepare a composition that *spontaneously* forms an aqueous, liquid, stable composition of non-crystalline particles when contacted with water.

Lafon fails to cure the deficiencies of Grebow. The Examiner relies upon Lafon for a disclosure of the levorotatory form of modafinil.

In view of the fact that Grebow, alone or in combination with Lafon, fails to teach or suggest each limitation of the rejected claims, Grebow and Lafon do not render the rejected claims obvious. Applicants respectfully request that this rejection be withdrawn.

Conclusion

Applicants respectfully submit that each rejection has been addressed. It is believed that all the claims are in form for allowance, and an early notification to that end is respectfully requested. Applicants invite the Examiner to contact the undersigned at (610) 883-5679 to clarify any remaining issues.

Respectfully submitted,

Date: August 4, 2006

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